UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ROSLYN HARRIS, on behalf of herself and all others similarly situated, Plaintiff, v. PFIZER INC., Defendant.	Civil Action No. 1:21-cv-06789

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT PFIZER INC.'S MOTION TO DISMISS PLAINTIFF'S COMPLAINT

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INTRODUCTION

Cigarette smoking is the single most preventable cause of death in the United States. It causes more than 480,000 deaths in the U.S. each year—one in five deaths. Cigarette smoking causes an even greater proportion of cancer deaths each year—one in three. For that reason, medical organizations and government agencies universally agree that the most important thing a smoker can do to reduce the risk of cancer and death is to quit smoking. Yet, millions of smokers struggle to quit because smoking is highly addictive.

Chantix (varenicline) is a highly effective prescription medicine that helps patients quit smoking. When the U.S. Food and Drug Administration ("FDA") approved Chantix for use in 2006, it proclaimed that Chantix was a "significant potential benefit to public health." *See* Gulliver Declaration, dated October 21, 2021 ("Gulliver Decl."), Ex. 1.[1] Two years later, the United States Public Health Service concluded that Chantix was the ***single most effective*** smoking cessation therapy on the market. By helping patients successfully quit smoking, Chantix has also significantly reduced their risk of cancer and other serious health conditions. The medicine also has a strong safety record, supported by an extensive clinical program and more than 15 years of real-world use globally. During that time, no medical, scientific, or regulatory body has suggested that Chantix could cause or increase the risk of cancer.

[1] All exhibits referenced herein refer to the exhibits attached to the Gulliver Decl. Additionally, citations for the judicially noticeable facts stated in the Introduction are included below in the Background section. Regarding the exhibits, the Court may consider information from government agencies, including FDA and Centers for Disease Prevention and Control ("CDC"), in evaluating Plaintiff's Complaint as matters of public record. *See, e.g.*, *In re Zyprexa Prods. Liab. Litig*., 549 F. Supp. 2d 496, 501 (E.D.N.Y. 2008) (judicial notice can be taken of "[p]ublic documents issued by government agencies such as the Food and Drug Administration"); *McDonnell v. First Unum Life Ins. Co*., 2013 WL 3975941, at *16 n.33 (S.D.N.Y. Aug. 5, 2013) (taking judicial notice of information on the CDC website); *Geller v. de Blasio*, 2020 WL 2520711, at *2 n.1 (S.D.N.Y. May 18, 2020) ("The Court may take judicial notice of relevant matters of public record" and relying on public health statistics reported by the City of New York) (J. Cote); *Our Wicked Lady LLC v. Cuomo*, 2021 WL 915033, at *1 n.2 (S.D.N.Y. Mar. 9, 2021) (same) (J. Cote). Additionally, "[a] court may take judicial notice of information publicly announced on a party's website, as long as the website's authenticity is not in dispute and 'it is capable of accurate and ready determination.'" *Wells Fargo Bank, N.A. v. Wrights Mill Holdings, LLC*, 127 F. Supp. 3d 156, 167 (S.D.N.Y. 2015).

In 2018, FDA began investigating the potential presence of nitrosamines in medicines. Nitrosamines are organic compounds common in water and foods, including cured and grilled meats, dairy products, and vegetables. Because nitrosamines are ubiquitous in the environment, nearly every human is exposed to some level of nitrosamines in their daily lives. Certain nitrosamines—several of which are present in cigarettes—are classified by the World Health Organization ("WHO") as probable or possible human carcinogens (i.e., substances that could cause cancer in humans).

In evaluating nitrosamine levels in medicines, FDA and other regulators have established acceptable intake limits ("ADI"), which extrapolate the amount a person could ingest every single day for her entire life without increasing her theoretical cancer risk associated with the exposure above 1 in 100,000. The ADI assume that a person will take the medicine ***every day for 70 years***. Because patients are typically prescribed Chantix for twelve to twenty-four weeks only, the 70-year daily intake assumption used to set FDA's ADI limits does not reflect how Chantix is actually prescribed and used: for weeks, not decades.

Nonetheless, in July and August 2021, after testing of Chantix identified the presence of a newly discovered nitrosamine called N-nitroso-varenicline, Pfizer voluntarily recalled consumer lots of the product and offered patients reimbursement for the cost of any unused Chantix. In September 2021, Pfizer further expanded the voluntary recall to include all Chantix lots. FDA press releases at the time informed patients that "there is no immediate risk to patients taking this medication. ***The health benefits of stopping smoking outweigh the theoretical potential cancer risk*** from the nitrosamine." Ex. 2. Moreover, as FDA acknowledged, "[t]here are ***no data available to directly evaluate the carcinogenic potential of N-nitroso-varenicline***." Ex. 15. Thus,

the decision to voluntarily recall Chantix was a precautionary measure, not based on evidence of any actual cancer risk associated with real-world use of the medication.

In the wake of this precautionary, voluntary recall, Plaintiff Roslyn Harris filed this consumer class action lawsuit, alleging that she is concerned about getting cancer from Chantix, which she allegedly was prescribed to help her quit smoking. She alleges that the Chantix she purchased was "economically worthless" and "unfit for human consumption" because it contained a nitrosamine. But, as pled, the Complaint is devoid of key factual allegations necessary for Plaintiff's claims to be viable—such as whether she consumed the Chantix she purchased, when she purchased it and for what price, whether she has taken advantage of the reimbursement offered by Pfizer, and whether she has developed cancer. As a result, the bare bones Complaint contains numerous pleading deficiencies subjecting it to dismissal.

First, Plaintiff has not alleged a cognizable injury. If she did not consume Chantix, she can be reimbursed by Pfizer. If she did, Plaintiff obtained the intended benefit of Chantix and received assistance in reducing her consumption of tobacco (which is proven to significantly increase the risk of cancer) by consuming Chantix with no proven risk of cancer. Thus, Plaintiff does not have Article III standing, and further lacks standing to pursue injunctive relief since she will not be subject to future harm.

Second, because the bulk of the claims set forth in the Complaint rely on a failure-to-warn products liability theory, Plaintiff was required to bring those claims under the New Jersey Products Liability Act ("NJPLA")—the exclusive cause of action for New Jersey consumers who allege injuries by a defective product. Because she failed to do so, all of Plaintiff's claims, except for her breach of express warranty claim, are subsumed by the NJPLA and should be dismissed.

Third, Plaintiff has not plausibly alleged her breach of warranty, fraud, violation of the New Jersey Consumer Fraud Act ("NJCFA") and unjust enrichment claims. Plaintiff's breach of express warranty claim fails because she has not alleged any express warranty made by Pfizer to her or her prescribing physician. In addition, Plaintiff's breach of implied warranty claim fails because she cannot plausibly allege that Chantix is unfit for its intended purpose—smoking cessation.

Plaintiff's fraud-based claims fail for multiple reasons. The only factual allegation Plaintiff asserts in support of these claims is the existence of the voluntary recall, but that allegation alone does not satisfy Rule 12(b)(6), let alone the heightened pleading standard of Rule 9(b). Plaintiff also has not pled a misstatement or fraudulent intent.

Plaintiff cannot state an unjust enrichment claim where her claim is duplicative of her other claims and she has not alleged a benefit that she conferred directly on Pfizer.

For all these reasons, the Court should dismiss Plaintiff's Complaint in its entirety and with prejudice.

BACKGROUND[2]

A. Cigarette Smoking Causes Cancer.

Tobacco use, particularly cigarette smoking, is the single most preventable cause of death in the United States. Ex. 1. Each year, cigarette smoking causes more than 480,000 deaths in the United States—about one in every five deaths. Ex. 3. Many of the health risks of smoking arise because tobacco smoke contains at least 70 chemicals—including tobacco-specific nitrosamines—

[2] This Background section assumes the well-pled allegations contained in the Complaint are true only for purposes of this motion, unless they are contradicted by other allegations, documents referenced in the Complaint, or other judicially noticeable facts.

that cause cancer. Ex. 4. Overall, one in three cancer deaths is caused by smoking (Ex. 5), and, on average, smokers die 10 years earlier than nonsmokers. Ex. 6.

Quitting smoking ***significantly decreases*** an individual's risk of getting cancer. According to the CDC:

> Quitting smoking lowers the risks for cancers of the lung, mouth, throat, esophagus, and larynx. ... Within 5 years of quitting, your chance of getting cancer of the mouth, throat, esophagus, and bladder is cut in half. Ten years after you quit smoking, your risk of dying from lung cancer drops by half. If nobody smoked, one of every three cancer deaths in the United States would not happen. (Ex. 7).

B. Quitting Smoking is Difficult.

While nearly 7 in 10 adult cigarette smokers want to stop smoking, less than 8% are successful. Ex. 6. It is a "very difficult" habit to break because nicotine, the active ingredient in cigarette smoke, is highly addictive. Ex. 1 at 1. Approximately 34 million American adults and more than a billion people worldwide are addicted to nicotine. Exs. 6-9. The high relapse rate of smokers seeking to quit also is attributable to a failure to use proven smoking cessation interventions, such as Chantix. Ex. 9 at 24.

C. Chantix is Safe and Effective.

On May 11, 2006, after finding that Chantix had "significant potential benefit to public health," FDA approved the medication as the first new smoking cessation treatment to enter the U.S. market in more than a decade. Ex. 1 at 1. Chantix is intended for short-term use only. As prescribed and stated on the label, Chantix is designed to be taken for 12 or 24 weeks total. Exs. 10, 16. In 2020, the CDC explained that "[V]arenicline [Chantix] … [is] ***much safer*** than smoking. … If you keep smoking, you will keep getting exposed to the hundreds of harmful chemicals in cigarette smoke. Quit-smoking pills are used for a short time compared to continuing to smoke." Ex. 11 (emphasis added).

Before Chantix, there was a significant unmet need for treatment options to help smokers break their addiction to tobacco. The only forms of FDA-approved smoking cessation therapies were nicotine-replacement therapies ("NRT") and bupropion, a medication originally developed and marketed as an antidepressant. Ex. 9 at 17; *see also* Ex. 12 at 44. Just two years after its introduction, the United States Public Health Service concluded that Chantix was the single most effective smoking cessation therapy on the market. Ex. 12 at 109, 121.

Chantix has a "long track record" of demonstrated efficacy and "safe[ty]." Ex. 11. Chantix has been studied extensively in more than 200,000 smokers in the past fifteen years. Ex. 13.

D. FDA's Investigation of Nitrosamines in Medicines.

Nitrosamines are a class of organic compounds having the chemical structure of a nitroso group bonded to an amine. Ex. 14 at 3. Nitrosamines are ubiquitous in the environment; they are common in water and foods, including cured and grilled meats, dairy products, and vegetables. Ex. 17. "Everyone is exposed to some level of nitrosamines." *Id.* Certain nitrosamines are classified as probable or possible human carcinogens by the International Agency for Research on Cancer based on laboratory testing, such as rodent carcinogenicity studies. Ex. 14 at App'x B; *see also* Ex. 2.

While nitrosamines are ubiquitous in the environment, FDA did not anticipate that nitrosamines would be present in drug products. Ex. 14 at 1. FDA is still "working to determine the source of these impurities." Ex. 15. By February 2021, it had identified seven potential nitrosamines that theoretically could be present in drug products. Ex. 14 at 4.

In response to the unexpected discovery of the potential presence of nitrosamines in other companies' medicines, in September 2020, FDA published a non-binding Nitrosamine Guidance document ("Nitrosamine Guidance") for industry, which it updated in February 2021. Ex. 14. The Nitrosamine Guidance does not establish legally enforceable responsibilities; instead, it reflects

FDA's "current thinking" and "should be viewed only as recommendations." *Id.* at 2. The Nitrosamine Guidance recommends that pharmaceutical manufacturers take steps to detect and prevent unacceptable levels of nitrosamines. *Id.* at 1.

E. ADI for Certain Nitrosamines, Including N-Nitroso-Varenicline.

FDA has published ADI for certain nitrosamines. *Id.* at 10. The ADI represents the daily intake level, which, if consumed every day for a period of ***70 years***, could create a theoretical lifetime cancer risk of 1 in 100,000. *Id.* at App'x B.

A series of assumptions inform the FDA's calculation of the ADI and are common across all nitrosamines. *Id.* FDA uses the most conservative carcinogenicity data available for the specific nitrosamine at issue. *Id.* The calculation of the ADI assumes that the exposed person weighs approximately 110 pounds and will take the medicine daily for 70 years. *Id.* Because of these assumptions, FDA acknowledges that, "[a] drug product intended for only short-term use … poses ***less risk*** than a drug product intended for chronic use." *Id.* at n.30.

The portion of the ADI calculation that varies across nitrosamines is the amount, in grams, of specific nitrosamine that results in a 50% tumor incidence rate in the laboratory animal most sensitive to that nitrosamine (*e.g.*, rats): a value called the "TD_{50}." *Id.* at App'x B. Because N-nitroso-varenicline was not a previously known nitrosamine, there was "no data available to directly evaluate [its] carcinogenic potential" that would establish a TD_{50}, and, thus, the ADI is not based on N-nitroso-varenicline data. Ex. 15; *see also* Ex. 14 at App'x B. As a result, as advised in the Nitrosamine Guidance and reported by FDA, "information available on closely related nitrosamine compounds was used to calculate lifetime exposure limits for N-nitroso-varenicline." Ex. 15. In other words, data based on ***another*** nitrosamine was used to calculate N-nitroso-varenicline's ADI—under the assumption that the comparison nitrosamine will have a similar carcinogenicity profile. Ex. 14 at App'x B.

Based on these assumptions, the calculated ADI for N-nitroso-varenicline is 37 ng / day. Ex. 18; *see also* Ex. 14, at App'x B. Thus, a 110-pound female who were to consume 37 ng of N-nitroso-varenicline ***every day for 70 years*** would have a theoretical (albeit unproven) 1 in 100,000 chance of developing cancer. In contrast, smoking causes one in three cancer deaths. Ex. 5 at 1.

F. The Discovery of N-Nitroso-Varenicline in Chantix.

From July to September 2021, despite FDA concluding that there was "no data available to directly evaluate the carcinogenic potential of N-nitroso-varenicline" (Ex. 15), Pfizer voluntarily recalled Chantix 0.5 mg and 1 mg tablets as a precautionary measure because they may contain levels of N-nitroso-varenicline above FDA's ADI. Ex. 2. Compl. ¶¶ 7, 8. Despite the voluntary recall, FDA informed patients that "***there is no immediate risk to patients taking [Chantix]***" since while "N-nitroso-varenicline ***may be*** associated with a potential increased cancer risk in humans," . . . [t]here are ***no data available to directly evaluate the carcinogenic potential of N-nitroso-varenicline***." Ex. 15 (emphasis added). Any theoretical "increased cancer risk [is] associated with long-term use," and Chantix is intended for short-term use only.

As such, FDA still advises patients "taking recalled [Chantix] … continue taking their [Chantix] until their pharmacist provides a replacement or their doctor prescribes a different medication that treats the same condition." Ex. 15. And, due to the obviously overwhelming cancer risk from smoking, FDA explained that "***[t]he health benefits of stopping smoking outweigh the cancer risk from the nitrosamine***." *Id.* (emphasis added).

G. Plaintiff's Allegations.

Plaintiff Roslyn Harris alleges that she purchased one Chantix "Starting Month" pack, which was subject to Pfizer's voluntary recall and reimbursement offer. Compl. ¶ 20; Ex. 19 ("Patients … should contact Stericycle … for instructions on how to … obtain reimbursement for

their cost").[3] While Plaintiff alleges that the Chantix she purchased "was unsafe" because it purportedly "contain[ed] dangerously high levels of N-nitroso-varenicline," *id.* ¶¶ 1–2, 29, 62, Plaintiff does not allege ***any*** of the following:

- how long she smoked;
- when she sought treatment for her smoking addiction;
- when she was prescribed Chantix;
- why she purchased Chantix;
- any specific language on the Chantix label that she or her prescribing physician relied upon in deciding to prescribe Chantix;
- when she filled her prescription and purchased Chantix;
- where she purchased Chantix;
- whether she paid for the Chantix;
- what price she paid for the Chantix;
- how long she was prescribed Chantix;
- whether she consumed the Chantix as prescribed, or at all;
- whether she was reimbursed for her Chantix; or
- what she did with the Chantix that was recalled.

Plaintiff alleges no physical injury caused by Chantix. Instead, she claims that Chantix is allegedly "worthless" due to the voluntary recall and seeks the return of her purchase price, along with statutory and punitive damages. *Id.* ¶¶ 42, 67, 82.

LEGAL STANDARD

Pfizer brings this motion pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). Under Rule 12(b)(1), "[a] case is properly dismissed for lack of subject-matter jurisdiction … when the district court lacks the statutory or constitutional power to adjudicate it."

[3] Plaintiff's Complaint is founded on Pfizer's recall, thus that recall notice is proper for judicial notice as it integral to the Complaint and incorporated therein. *Becker v. Cephalon, Inc.*, 2015 WL 5472311, at *4 (S.D.N.Y. Sept. 15, 2015) (exhibits that are integral to the complaint and clearly replied upon in it may be considered on a motion to dismiss even though they were not attached to the complaint).

Makarova v. U.S., 201 F.3d 110, 113 (2d Cir. 2000). Courts lack jurisdiction when the plaintiff does not have Article III standing. *In re Bibox Grp. Holdings Ltd. Sec. Litig.*, 2021 WL 1518328, at *5 (S.D.N.Y. Apr. 16, 2021) (Cote, J.). The plaintiff bears the burden of establishing standing. *Makarova*, 201 F.3d at 113.

Under Rule 12(b)(6), a complaint must be dismissed if it does not "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "Although the Court must still accept factual allegations as true, it should not credit 'mere conclusory statements' or 'threadbare recitals of the elements of a cause of action.'" *Stephenson v. Citco Grp. Ltd.*, 700 F. Supp. 2d 599, 618-19 (S.D.N.Y. 2010) (quoting *Iqbal*, 556 U.S. at 678).

ARGUMENT

I. PLAINTIFF HAS NOT PLED AN INJURY AND THUS LACKS STANDING.

This lawsuit, based solely on Pfizer's precautionary decision to issue a voluntary recall of Chantix due to the presence of a nitrosamine, is a classic "no harm" consumer products liability claim. Plaintiff does not allege a physical injury caused by the medication. Nor does she allege that her Chantix did not work as intended. Instead, Plaintiff claims that she has suffered an economic harm (purchasing a purportedly "worthless" medication) and seeks the return of her purchase price. *See* Compl. ¶ 42. But Plaintiff has not suffered any cognizable injury, and Pfizer has offered reimbursement to patients for unused Chantix. Ex. 19. As such, Plaintiff lacks standing and all of her claims must be dismissed.

A. Plaintiff Cannot State a Claim for Fraud, Violation of the NJCFA, or Breach of Express or Implied Warranty Without an Injury.

To state a claim for fraud, violation of the NJCFA, and breaches of warranty, Plaintiff must plead an injury. A NJCFA claim requires the plaintiff to assert an "ascertainable loss." *Hoffman*

v. Nordic Nats., Inc., 2014 WL 1515602, at *5 (D.N.J. Apr. 17, 2014). To demonstrate an ascertainable loss, a plaintiff must establish "actual loss" that is "quantifiable or otherwise measurable," or "real and demonstrable," as opposed to "hypothetical or illusory" or "speculative." *Thiedemann v. Mercedes-Benz USA, LLC*, 872 A.2d 783, 792, 794-796 (N.J. Sup. Ct. 2005). Plaintiff's fraud and warranty claims similarly require "damages." *Hoffman*, 2014 WL 1515602, at *5, 7 (dismissing NJCFA, fraud and warranty claims for failure to plead injury).

As an initial matter, Plaintiff fails to adequately plead the facts of her purchase required to establish a consumer injury. For example, in *Colella v. Atkins Nutritionals, Inc.*, the court held that the plaintiff's claim for a violation of New York consumer protection statutes failed in part because "Plaintiff provide[d] limited detail regarding the purchases of the three … products that form[ed] the basis of the complaint. He fail[ed] to allege with specificity where he purchased the products, when he purchased the products, or what he paid for the products." 348 F. Supp. 3d 120, 142 (E.D.N.Y. 2018); *see also Solo v. Bed Bath & Beyond, Inc.*, 2007 WL 1237825, at *3 (D.N.J. Apr. 26, 2007) (dismissing NJCFA claim; "Plaintiff is required to plead specific facts setting forth and defining the ascertainable loss suffered"); *Lieberson v. Johnson & Johnson Consumer Cos., Inc.*, 865 F. Supp. 2d 529, 541-42 (D.N.J. 2011) (dismissing NJCFA claim; "Plaintiff has not alleged the price she paid for the Products."). So too here. Plaintiff alleges only that she "purchased a Chantix 'Starting Month' pack." Compl. ¶ 20. Such a conclusory allegation of a purchase is inadequate to state a claim and demonstrate standing.

But no amount of further factual detail could overcome the fundamental defect at the core of Plaintiff's claims—she suffered no injury. A plaintiff suffers no economic injury where, "[b]y plaintiffs' own admission, [she] paid for an effective [product], and she received just that—the benefit of her bargain." *Rivera v. Wyeth-Ayerst Laboratories* is also instructive. 283 F.3d 315,

320 (5th Cir. 2002). "Without alleging that a product failed to perform as advertised, a plaintiff has received the benefit of his bargain and has no basis to recover purchase costs. ... Those patients who purchased [the medication] ... and who obtained effective pain relief … received the 'benefit of their bargain.'" *Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d 171, 176 (D.D.C. 2003) (dismissing claims).

The face of Plaintiff's Complaint demonstrates that Plaintiff was not injured. A product is not "worthless" if it served its intended purpose, and Plaintiff does not and cannot claim that Chantix failed to serve its intended purpose. FDA urges consumers to continue taking Chantix until a replace therapy can be prescribed because "***there is no immediate risk to patients taking [Chantix]***" and [t]here are ***no data available to directly evaluate the carcinogenic potential of N-nitroso-varenicline***." Exs. 15, 2, 18. So if Plaintiff consumed her Chantix, she obtained the intended benefit of the medicine for smoking cessation. Moreover, if Plaintiff consumed Chantix and quit smoking, she greatly lowered her overall health risks. *See* Ex. 2 (September 2021 FDA Chantix Recall Announcement advising patients that "***any possible risk presented by N-nitroso-vareniclines is far less than the health risks presented by smoking***") (emphasis added). If Plaintiff did not consume her Chantix, she can receive a refund from Pfizer for any unused product. Ex. 15. Thus, Plaintiff has not been injured.

B. Plaintiff Lacks Article III Standing.

Because Plaintiff has not been injured, the Court should dismiss the Complaint under Rule 12(b)(1) for lack of Article III standing. At an "irreducible constitutional minimum," Article III requires Plaintiff to show she has ***personally suffered*** some actual or threatened injury due to defendant's conduct and that the injury is "fairly traceable" to the challenged action" and is "likely … [to be] redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992); *see also In re Bibox Grp.*, 2021 WL 1518328, at *5. Plaintiff has not done so here. For

example, in *Rivera*, a pharmaceutical manufacturer voluntarily withdrew Durcat from the market after receiving reports of liver failure among long term users. 283 F.3d at 317. Plaintiffs sought to represent all patients "who were prescribed, had purchased, and had ingested Duract but suffered *no* physical or emotional injury." *Id.* (emphasis in original). Plaintiffs did not claim that "Duract was ineffective as a pain killer or ha[d] any future health consequences." *Id.* "Instead, they assert[ed] that their loss of cash [wa]s an 'economic injury.'" *Id.* at 319. The Fifth Circuit disagreed and dismissed the case for lack of standing because "[m]erely asking for money does not establish an injury in fact." *Id.* The court explained:

> [T]he plaintiffs' attempt to recast their product liability claim in the language of contract law. The wrongs they allege-failure to warn and sale of a defective product-are products liability claims … Yet, the damages they assert-benefit of the bargain, out of pocket expenditures-are contract law damages. The plaintiffs apparently believe that if they keep oscillating between tort and contract law claims, they can obscure the fact that they have asserted no concrete injury. Such artful pleading, however, is not enough to create an injury in fact.

Id. at 320-21.

Similarly, in *James v. Johnson & Johnson Consumer Companies*, purchasers of baby shampoo filed a consumer class action against the product's manufacturer, alleging that the manufacturer included a toxic ingredient in the shampoo. 2011 WL 198026 at *2 (D.N.J. Jan. 20, 2011). The plaintiffs did not allege that their children suffered any physical harm from the shampoo; rather, the purchasers attempted to establish standing by alleging that they suffered economic harm because they would not have purchased the shampoo had they known of its alleged toxicity. *Id.* The court rejected this theory of standing, holding that the purchasers failed to establish an injury-in-fact. *Id.* The court explained that "[o]nce the product had been consumed ... there was no economic injury for Plaintiffs to complain of, and the fear of future injury is legally insufficient to confer standing. Plaintiffs received the benefit of their bargain so long as there were

no adverse health consequences, and the product worked as intended, meaning that the hair of Plaintiff's children was cleansed, and their eyes and skin were not irritated." *Id.*

Like the plaintiffs in *Rivera* and *James*, Plaintiff received the benefit of her bargain and has no valid claim of injury, economic or otherwise. She lacks Article III standing, and for this reason, the Complaint should be dismissed in its entirety.

C. Plaintiff Lacks Standing to Seek Injunctive Relief.

Plaintiff's request for injunctive relief also fails because she has not alleged a risk of future harm. To obtain injunctive relief, "a plaintiff must show a likelihood that he will be injured in the future." *Carver v. City of N.Y.*, 621 F.3d 221, 228 (2d Cir. 2010) (internal quotation omitted). "Past injuries . . . do not confer standing to seek injunctive relief unless the plaintiff can demonstrate that she is likely to be harmed again in the future in a similar way." *Kommer v. Bayer Consumer Health*, 710 F. App'x 43, 44 (2d Cir. 2018) (*quoting Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 239 (2d Cir. 2016)).

Plaintiff has not alleged that she is likely to be harmed in a similar way. Plaintiff does not allege that she is being targeted or subjected to alleged ongoing misconduct by Pfizer, nor does she allege any ongoing use of Chantix that would subject her to the possibility of future harm. Instead, she asserts only that Pfizer "has acted or refused to act on grounds generally applicable to the Class … as a whole." Compl. ¶ 33. But "[t]here is no exception to demonstrating future injury when the plaintiff is pursuing a class action." *Buonasera v. Honest Co.*, 208 F. Supp. 3d 555, 564 (S.D.N.Y. 2016).

Even if Plaintiff had pled that she intended to purchase Chantix again, she would still not have standing for two reasons. First, Plaintiff's allegations demonstrate that she is already aware of the alleged increased "risk" of cancer and thus cannot assert that she will be misled in the future. *See, e.g.*, *Marino v. Coach, Inc.*, 264 F. Supp. 3d 558, 565 (S.D.N.Y. 2017) (once plaintiffs know

the true price of a product, "they cannot be misled"). Moreover, Pfizer voluntarily recalled all lots of Chantix, so there is nothing to enjoin. *See Nicosia*, 834 F.3d at 239 (injunctive relief improper because Amazon had stopped selling the product). Accordingly, Plaintiff's request for injunctive relief must be dismissed.

II. THE NJPLA SUBSUMES ALL BUT ONE OF PLAINTIFF'S CLAIMS.

Even if Plaintiff pled a cognizable injury and had standing, the NJPLA subsumes every claim except for her express warranty claim. The NJPLA is "the sole method to prosecute a product liability action." *Tirrell v. Navistar Int'l, Inc.*, 248 N.J. Super. 390, 398–99 (App. Div. 1991), cert. denied, 126 N.J. 390 (1991). The NJPLA was enacted "to limit the expansion of products-liability law" and "to limit the liability of manufacturers so as to balance[] the interests of the public and the individual with a view towards economic reality." *Zaza v. Marquess & Nell, Inc.*, 144 N.J. 34, 47 (1996) (quotations and citations omitted). A product liability action is "any claim or action brought by a claimant for harm caused by a product, ***irrespective of the theory underlying the claim***, except actions for harm caused by breach of an express warranty." N.J. Stat. Ann. § 2A:58C–1(b)(3) (emphasis added). Thus, under New Jersey law, a plaintiff only has a compensable loss for a harm caused by a product if she can allege "personal injury" or "physical damage to property other than the product itself." N.J.S.A. 2A:58C-1(b)(2).

Here, Plaintiff has pled neither personal injury not physical damage. Instead, she seeks to "shoehorn" her "failure to warn" "allegations into other causes of action" when "it is clear from the innumerable boilerplate allegations that h[er] claims sound in products liability causes of action." *Barrett v. Tri-Coast Pharm., Inc.*, 518 F. Supp. 3d 810, 824 (D.N.J. 2021). This attempt fails. As the New Jersey Supreme Court has explained:

> Were there any doubt about the essential nature of the claims asserted by plaintiffs, a careful reading would demonstrate that they sound in products liability causes of action. The central focus of plaintiffs' complaints is that

> defendants were aware of dangers associated with lead—and by extension, with the dangers of including it in paint intended to be used in homes and businesses—and failed to warn of those dangers. ***This classic articulation of tort law duties, that is, to warn of or to make safe, is squarely within the theories included in the PLA.***

In re Lead Paint Litig., 924 A.2d 484, 503–04 (N.J. 2007) (tort claim subsumed by the NJPLA) (emphasis added); *see also Indian Brand Farms v. Novartis Crop Prot., Inc.*, 890 F. Supp. 2d 534, 548 (D.N.J. 2012) (finding plaintiff's NJCFA and fraudulent misrepresentation claims were subsumed by the NJPLA because they were based on facts that supported a failure to warn claim).

For example, in *O'Donnell v. Kraft Foods, Inc.*, the plaintiffs brought a consumer class action asserting a violation of the NJCFA and alleging that defendant's hot dogs would increase plaintiffs' risk of cancer and that they were not warned of the carcinogenic dangers. 2010 WL 1050139, at *3 (D.N.J. Mar. 18, 2010). The Court dismissed the complaint as subsumed by the NJPLA and held that:

> Plaintiffs are seeking damages … due to the increased risk of cancer they allege arises from consumption of a product. Plaintiffs' attempt to tack a [consumer fraud] remedy onto the underlying products liability claim does not alter the analysis: their theory that they are entitled to recovery of their purchase price for the hot dogs depends upon Defendants' ***alleged failure to warn of their increased risk of cancer***, a failure of "adequate warnings or instructions" covered by the PLA.

Id. at *3 (emphasis added).

Similarly, in *Barrett*, the plaintiff brought fraud and warranty claims due to an infection he suffered because of his medication's purported bacterial contamination. 518 F. Supp. 3d at 824. The court rejected the plaintiff's attempt to "shoehorn his [product liability] allegations into other causes of action" when the case was "premised on the product being defective" and thus was a "failure to warn" case. *Id.* The court also noted that the fraud-based claims were subsumed by the NJPLA "because the alleged misrepresentation would not be actionable if … [the] pharmaceuticals were not contaminated." *Id.*; *see also Darby v. Merck & Co.*, 949 A.2d 223, 276-277 (N.J. Super.

Ct. App. Div. 2008) (consumer fraud claims subsumed because "the gravamen of [the] claim [i]s that [a pharmaceutical company] marketed [a medicine] fully aware of its … risk[s] [and] made misrepresentations[ ] and ... omis[sions]" in connection with its marketing"); *Mendez v. Shah*, 28 F. Supp. 3d 282, 302 (D.N.J. 2014) (fraud and misrepresentation claims subsumed because "[a]lthough [the] plaintiff stresses the representations made by" the defendant, including "safe and effective use," the "essence of her claim is that the misrepresentations resulted in physical harm from the product").

The same result follows here. The Complaint centers around Plaintiff's allegation that Pfizer failed to warn her that Chantix "contain[s] unsafe levels of N-nitroso-varenicline." Compl. ¶ 18; *see also id.* ¶¶ 25– 26, 29, 41, 47, 60–65, 77–80. Thus, her "alleged misrepresentation would not be actionable if … [the] pharmaceuticals were not contaminated." *Barrett*, 518 F. Supp. at 824. The NJPLA provides the sole basis for potential relief here and Plaintiff's NJCFA, implied warranty, fraud and unjust enrichment claims must be dismissed.

III. PLAINTIFF FAILS TO STATE AN EXPRESS WARRANTY CLAIM.

Plaintiff's claim for breach of express warranty is the only claim not subsumed by the NJPLA. But it too fails. As discussed above, Plaintiff's express warranty claim fails because she has not pled an injury. It also fails because she has not pled an express promise or any reliance on such a promise. To state a claim for express warranty, Plaintiff must allege "(1) that Defendant made an affirmation, promise or description about the product; (2) that this affirmation, promise or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description." *Hindermyer v. B. Braun Med. Inc.*, 419 F. Supp. 3d 809, 829 (D.N.J. 2019).

Plaintiff's express warranty claim fails because she does not allege a false "affirmation of fact or promise." *Simmons v. Stryker Corp.*, 2008 WL 4936982, at *2 (D.N.J. Nov. 17, 2008). A

plaintiff must allege "sufficient factual allegations about the nature of the express warranty." *Id.* For example, in *Simmons*, the plaintiff alleged that the defendant warranted "that their device was a safe and effective ambulatory drug delivery system." *Id.* The court dismissed the claim, holding that it was "devoid of any 'factual matter' to support the existence of an express warranty." *Id.*; *see also Delaney v. Stryker Orthopaedics*, 2009 WL 564243, at *5 (D.N.J. Mar. 5, 2009) (dismissing express warranty claims against medical device manufacturer because plaintiff did not "establish how or by whom a promise was made nor what exactly was promised").

So too here. The Complaint alleges that Pfizer purportedly promised "that the product would contain only what was stated on the label, and not harmful impurities such as N-nitroso-varenicline." Compl. ¶¶ 36, 38. But Plaintiff does not point to any specific label statement that makes these alleged promises. In fact, a review of the Chantix label makes plain that it does not make such claims. *See* Exs. 10, 16.[4] Plaintiff fails to state an express warranty claim.

IV. PLAINTIFF FAILS TO ALLEGE A BREACH OF IMPLIED WARRANTY.

As discussed above, Plaintiff's implied warranty claim fails because she has not pled an injury and because it is subsumed by the NJPLA. This claim also fails because Plaintiff does not allege that Chantix is unfit for its intended purpose: smoking cessation. To state an implied warranty claim, Plaintiff must allege "(1) that a merchant sold goods, (2) which were not 'merchantable' at the time of sale, (3) injury and damages to the plaintiff or its property, (4) which were [ ] caused proximately and in fact by the defective nature of the goods, and (5) notice to the seller of injury." *Hoffman*, 2014 WL 1515602, at *7 (quoting *Marcus v. BMW of N. Am., LLC*,

[4] Courts may take judicial notice of a drug's label in considering a motion to dismiss. *Becker*, 2015 WL 5472311, at *3. Additionally, Plaintiff repeatedly refers to the Chantix label in the Complaint, *see, e.g.*, Compl. ¶¶ 11, 20, 36, 61, making it suitable for consideration on a motion to dismiss. *Id.* at *4 (exhibits that are integral and replied upon are proper for judicial notice).

687 F.3d 583, 600 n.8 (3d Cir. 2012)). "Merchantability requires that a product conform to its ordinary and intended use." *Lieberson*, 865 F. Supp. 2d at 542. Court have determined that this means "the *general* purpose for which it should have been sold." *Id.* (emphasis in original).

Plaintiff's implied warranty claim fails because she has not alleged that Chantix was unfit for its general purpose of helping nicotine addicts quit smoking. *See* Compl. ¶¶ 46–47. Nor could she. Plaintiff's own Complaint relies upon FDA statements that demonstrate that FDA advises patients "taking recalled [Chantix] … [to] ***continue*** taking their [Chantix] until their pharmacist provides a replacement or their doctor prescribes a different medication that treats the same condition" because "***any possible risk presented by N-nitroso-vareniclines is far less than the health risks presented by smoking.*** Ex. 15 (emphasis added); *see also* Compl. at n.3–5, 7–8. In any event, FDA continues to emphasize that "[t]here are ***no data available to directly evaluate the carcinogenic potential of N-nitroso-varenicline***" (Ex. 15 (emphasis added)) and the theoretical potential cancer risks presented by N-nitroso-varenicline "pose[] ***less risk***" because Chantix is not "intended for chronic use." Ex. 15 at n.30 (emphasis added). Therefore, the implied warranty claim must be dismissed.

V. PLAINTIFF'S FRAUD-BASED CLAIMS FAIL FOR SEVERAL REASONS.

As discussed above, Plaintiff's NJCFA and common law fraud claims fail because they are subsumed by the NJPLA and she has not alleged an injury. These claims also fail because Plaintiff has not satisfied the heightened pleading standard of Rule 9(b) or adequately alleged a misstatement. Finally, Plaintiff's fraud claim and NJCFA claim to the extent it is based on omissions further fail because she has not alleged fraudulent intent.

A. Plaintiff's Fraud Claims Are Not Pled with Specificity.

Plaintiff's fraud-based claims are not pled with the required specificity under Rule 9(b). To satisfy Rule 9(b), Plaintiff must identify the "who, what, and where" of the alleged omission

and/or misrepresentation. Claims under the NJCFA claim must be pled in accordance with Rule 9(b). *Parker v. Howmedica Osteonics Corp.*, 2008 WL 141628, at *2 (D.N.J. Jan. 14, 2008) ("CFA claims 'sounding in fraud' are subject to the particularity requirements" of Rule 9(b)). These requirements may be satisfied "by pleading the date, place or time of the fraud." *Rait v. Sears, Roebuck & Co.*, 2009 WL 250309, at *4 (D.N.J. Feb. 3, 2009).

For example, in *Crozier v. Johnson & Johnson Consumer Cos.*, 901 F. Supp. 2d 494, 506 (D.N.J. 2012), the court dismissed plaintiffs' NJCFA claim for affirmative misrepresentations in Neosporin advertisements because the plaintiffs failed to plead when they saw the advertisements, when they bought the product and where they bought the product as required by Rule 9(b). *Id.*; *see also Fleisig v. ED&F Man Cap. Mkts., Inc.*, 2020 WL 3127875, at *2-3 (S.D.N.Y. Jun. 12, 2020) (J. Cote) (dismissing fraud claim for failure to identify who made the representation, when it was made, or describe the representation with sufficient precision); *Utts v. Bristol-Myers Squibb Co., et al.*, 251 F. Supp. 3d 644 (S.D.N.Y. 2017) (J. Cote) (plaintiffs failed to plead their state law fraud claims with the requisite particularity because they made only conclusory allegations regarding the fraudulent statements).

So too here. Plaintiff does not allege when she bought the product, what specific statements she (or her prescribing physician) reviewed, when they were made or when she (or her prescribing physician) were exposed to them. Instead, she asserts in an entirely conclusory fashion that "Defendant provided Plaintiff … with materially false or misleading information about the Chantix manufactured by Defendant." Compl. ¶ 77. This is insufficient.

B. Plaintiff Alleges No Misstatement by Pfizer.

Plaintiff has not alleged that Pfizer made any false statement of fact. To state a NJCFA claim, a plaintiff must allege unlawful conduct, which Plaintiff has alleged was a material misstatement that Chantix "would contain only the active ingredients stated on the label, and not

harmful, carcinogenic impurities such as N-nitroso-varenicline." *Id.* ¶ 60; *see also Zaman v. Felton*, 219 N.J. 199, 221-222 (2014) (internal citation omitted). Similarly, to state a claim for fraud, a plaintiff must allege a material misrepresentation of a presently existing or past fact. *Gennari v. Weichert Co. Realtors*, 691 A.2d 350, 367 (N.J. 1997).

Plaintiff has not alleged any false statement of fact. She has not identified any specific statement by Pfizer or detailed how that statement was purportedly false. Courts routinely dismiss NJCFA claims in similar circumstances. *See, e.g., Zottola v. Eisai Inc.*, 2021 WL 4460563, at *9 (S.D.N.Y. Sept. 29, 2021) (dismissing fraud claim because "Plaintiff plead[ed] generally that Defendants did not disclose the Medications' cancer risks … But this type of vague allegation, without more, is insufficient to plead a fraud"); *In Riddell Concussion Reduction Litig.*, 77 F. Supp. 3d 422, 438 (D.N.J. 2015) (dismissing claim; "Plaintiffs' failure to identify with specificity the marketing statements which they allege are false, which proved fatal under Rule 9(b), compels the same result under Rule12(b)(6)"); *Henderson v. Volvo Cars of N. Am., LLC*, 2010 WL 2925913, at *3 (D.N.J. July 21, 2010) (dismissing claim because plaintiffs "only made vague assertions with respect to their affirmative misrepresentation fraud claims").

C. Plaintiff Has Not Pled Fraudulent Intent.

Plaintiff's fraud claim and NJCFA claim (to the extent it relies on a purported omission (Compl. ¶ 62)), also fail because she has not alleged fraudulent intent. To state a claim for fraud, a plaintiff must allege fraudulent intent. *Weil v. Express Container Corp.*, 360 N.J. Super. 599, 612 (App. Div. 2003). And when "the alleged consumer fraud [for a NJCFA claim] consists of an omission, the plaintiff must sufficiently show that the defendant acted with knowledge and intent *is* an essential element of the fraud." *Cox v. Sears Roebuck & Co.*, 138 N.J. 2, 17 (1994) (emphasis in original); *see also Schechter v. Hyundai Motor Am.*, 2019 WL 3416902, at *6 (D.N.J. July 29, 2019) (dismissing NJCFA claim where plaintiff failed to allege an adequate basis to support the

allegation that defendants were aware of the defect or anonymous consumer complaints posted online); *Zottola* (dismissing fraud claim because "Plaintiff's allegations that Defendants 'knew' of and concealed the allegedly defective nature of the Medications, without more, are conclusory").

Here, Plaintiff has alleged no facts suggesting that Pfizer ***knew*** about the N-nitroso-varenicline in Chantix, let alone that Pfizer ***intended to withhold*** such information from Plaintiff. *See* Compl. ¶ 65. It is clear that FDA and others were surprised to discover nitrosamines in medicines and that N-nitroso-varenicline is a newly discovered nitrosamine. Ex. 14 at 1. Instead, Plaintiff simply speculates that Pfizer must have known and purposefully withheld such information because Pfizer voluntarily recalled Chantix. *See, e.g.*, Compl. ¶¶ 60, 62. Such rank speculation should be given no weight. Plaintiff's fraud-based claims must be dismissed.

VI. PLAINTIFF'S UNJUST ENRICHMENT CLAIM FAILS.

As discussed above, Plaintiff's unjust enrichment claim is subsumed by the NJPLA. In addition, it fails because New Jersey does not recognize it as an independent tort and because Plaintiff has not alleged that Pfizer received a benefit directly from her. To state an unjust enrichment claim, Plaintiff must allege that (1) Pfizer received a benefit from her, and (2) that the retention of the benefit by Pfizer is inequitable. *D.R. Horton Inc. – N.J. v. Dynastar Dev., L.L.C.*, 2005 WL 1939778, at *18 (N.J. Super. Ct. L. Div., Mercer Cnty. Aug. 10, 2005) (dismissing unjust enrichment claim). Plaintiff does not meet her burden.

First, Plaintiff's unjust enrichment claim should be dismissed because "New Jersey does ***not*** recognize unjust enrichment as an independent tort cause of action." *Warma Witter Kreisler, Inc. v. Samsung Elecs. Am., Inc.*, 2009 WL 4730187, at *7 (D.N.J. Dec. 3, 2009) (emphasis added). For example, in *Warma*, the plaintiff's "theory of recovery [wa]s based on the assertion that it was misled by [defendant] as to the fitness of the [product]." *Id.* The court dismissed the claim because the plaintiff's allegations "sound[ed] in tort." *Id.* Plaintiff here also asserts that she was misled

by Pfizer as to the fitness of the Chantix that she purchased. Such allegations sound in tort and require dismissal of her unjust enrichment claim.

Second, Plaintiff's unjust enrichment claim also fails because she did not confer a benefit directly upon Pfizer. "New Jersey law requires a direct relationship between the parties." *Maniscalco v. Brother Int'l Corp.*, 627 F. Supp. 2d 494, 505 (D.N.J. 2009) (dismissing unjust enrichment claim where plaintiff failed to allege that he conferred a benefit directly upon defendant). A "benefit conferred upon a retailer not sharing in profits with the product manufacturer ***does not result*** in the manufacturer's unjust enrichment." *Alin v. Am. Honda Motor Co.*, 2010 WL 1372308, at *15 (D.N.J. Mar. 31, 2010) (dismissing claim) (emphasis added). Here, Plaintiff does not allege a direct relationship between herself and Pfizer, which is fatal to her claim. *See, e.g.*, *Hale v. Stryker Orthopaedics*, 2009 WL 321579, at *4 (D.N.J. Feb. 9, 2009) (dismissing claim; plaintiffs received the products after making co-payments to their health insurers).

CONCLUSION

For the reasons stated herein, Pfizer respectfully requests that the Court dismiss the Complaint in its entirety and with prejudice.

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Respectfully submitted,

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